Arch Public Health
2004, 62, 83-106

Regulating Red and Green Biotechnologies in Belgium: Diverging Designs of Biopolicies

by

Varone F. & Schiffino N. [1]

Abstract

Our contribution aims to compare the Belgian public regulation of two biotechnology sectors: biomedicine (red biotechnology) and genetically modified organisms (GMOs, green biotechnology). The question that puzzles us is why GMO policy is more interventionist than the policy regarding assisted reproductive technologies (ART). Through documentary analyses, interviews and reputation approach, we highlight three main categories of explanation. First, the difference in terms of policy networks is of high relevance: a "policy community" in the field of biomedicine allows a looser regulation than the GMO "issue network". Second, polity peculiarities -such as the key role of political parties, the federalist structure and the (non) existence of an administrative agency- partly explain the differences between GMO- and ART- policies. Indeed, political parties adopt a more pro-active strategy towards GMO than biomedicine; federalism is implemented in a cooperative way and with a clear share of competencies in the GMO sector, but not in the case of ART; and while a Biosafety Agency ensures a multi-level coordination of GMO issues, such a centralising administration is still lacking for biomedicine. Thirdly, the pressure for harmonisation by the international and the European organisations is stronger in the agro-food and the

[1] Correspondence address: Université catholique de Louvain (Louvain-la-Neuve), Department of Social and Political Sciences, varone@spri.ucl.ac.be.; schiffino@spri.ucl.ac.be

environmental sector than in the biomedical sector. The generalisations that emerge from this analytical framework can help to formulate biopolicies in other sectors, such as genetic testing.

Keywords: *assisted reproductive technologies, biopolitics, biotechnologies, genetic testing, genetically modified organisms, public policies.*

Introduction: why different biopolicies in Belgium? [1]

The development of life sciences and related biotechnologies have stirred many hopes (e.g. new therapy for degenerative diseases, novel-food with higher nutritional quality) and, at the same time, many fears (e.g. eugenics, genetic pollution, "commercialisation of life"). Given its potential impact on everyday life, biotechnology has become a salient issue in the media and has been part of the political agenda since the 1970s (1, 2). The study of *biopolitics* addresses the political regulation of this new technology. The social scientific study of biopolitics focuses on how one might describe, explain and evaluate the public policies that regulate contentious biotechnological issues, such as reproductive engineering, stem cell and embryo research, organ (xeno-)transplantation, genetic screening and monitoring, genetically modified organisms, etc., which can collectively be labelled as *biopolicies* (3).

Belgium is a pioneering country in the development and commercialisation of various biotechnological innovations. As far as Belgian biopolicies are concerned, these vary considerably according to the sector in question. Indeed, the policy on *Assisted Reproductive Technologies (ART)* is obviously less interventionist than the policy concerning *Genetically Modified Organisms (GMO)* in the agro-food sector. This article aims to analyse the reasons behind this marked difference between the political regulation of red (biomedical) and green (agricultural) biotechnologies.

Historically, Belgium has been among the leading countries in ART. This pioneering status applies to Artificial Insemination (AI) as well as to In Vitro Fertilisation (IVF). Since the 1960s, R. Schoysman has been developing AI at the Vrije Universiteit Brussels (VUB). In 1983, the first

[1] A research project comparing the French and the Belgian regulation of genetically modified organisms (GMOs) and assisted reproductive technologies (ART) has been carried out by the authors thanks to the funding of the Belgian Federal Science Policy Office (See http://www.aurap.ucl.ac.be). The authors want here to acknowledge the financial support of the Belgian Federal Science Policy Office.

Belgian test tube baby was born as a result of IVF performed at the Katholieke Universiteit Leuven (KUL). Today, Intra-Cytoplasmic Sperm Injection (ICSI) is a well-known technique; it was first used at the VUB by P. Devroey's and A.C. Van Steirteghem's research team. In 1992, they reported the first successful birth using this technique.

ART centres developed without official licensing until 1999. For a long time, this situation led to Belgium having one of the highest densities of ART centres in the world. Even subsequent to the procedural regulations that were adopted in 1999, the country is still facing an 'oversupply'. There is strong economic competition between the most efficient (University) centres. Today, embryo and stem cell research is a very promising area of biotechnology (replacing tissue damaged by injuries or treating serious diseases such as Parkinson's). Thus, competition between scientists will certainly increase in the future.

Furthermore, at first glance, Belgium seems to be a so-called "bioethical paradise" for those who want to practice (doctors) and to have access (patients) to ART with a minimum of restrictions (Table 1). Physicians are self-regulated as far as the hospital rules for ART practices are concerned, and the recent law of 11 May 2003 allows them to conduct research on *in vitro* embryos and therapeutic cloning. The access to ART for patients is also very high. Married, cohabiting couples, single parents and hetero- or homosexual couples, choose the ART-centre that meets their specific needs. Moreover, the Social Security system has recently broadened the insurance coverage (Royal Decree of 4 April 2003). Medical acts (gynaecological practices and medicine) as well as laboratory work (such as ICSI) are now reimbursed. Considering both the large autonomy of target groups and the high access of final beneficiaries, the policy design is clearly less interventionist than the ART-policies adopted by France, Spain, the United Kingdom or the Netherlands, as well as by very restrictive countries such as Germany, Switzerland or Norway (4).

Belgium also played a pioneering role in the area of R&D on agro-food GMOs. The scientific community attributes the first genetically modified plant to M. Van Montagu (University of Gent), in collaboration with J. Schell (Gent) and H. Goodman of the San Francisco Medical School. In 1983, these researchers implemented the first vegetal transgenesis and, subsequently, obtained transgenetic tobaccos resistant to the antibiotic *kanamycine* (5). Also, M. Van Montagu has created, along with his collaborators, a spin-off called "Plant Genetic Systems" (PGS). In the industrial process of implanting biotechnology companies in Belgium, the success of PGS has offered much encouragement. Indeed,

PGS is still acknowledged as such, in spite it being bought by Aventis and subsequently Bayer.

To this day, apart from the activities of private companies, several universities invest their efforts in GMOs, in particular, the Vlaams Interuniversitair Instituut voor Biotechnologie (VIB, Ghent), the Facultés Universitaires des sciences agronomiques de Gembloux, the Katholieke Universiteit Leuven (KUL) and the Universiteit Gent (RUG). Also, Belgium, and in particular (West) Flanders, remains a relatively important area – considering the size of the country compared to other European states – for the location of companies, amongst others Bayer Crop Science (formerly Aventis), Monsanto, AgrEvo (PGS/Hoechst), Advanta SES, Novartis Seeds and Syngenta.

Nevertheless, Belgium is certainly not a bioethical paradise for the private firms that wish to produce and commercialise GMOs. As a matter of fact, the interventionist Belgian regulation imposes numerous conditions for the contained use and deliberate release of GMOs (Table 1). The regional Ministers of Environment manage the authorisation for laboratory research on GMOs. At the federal level, the Biosafety Council gives advice to the Minister of Public Health, Consumer Protection and the Environment, who regulates field experiments, the production and commercialisation of GMOs. Finally, the Federal Food Safety Agency is responsible for the *ex post* control of deliberate release and labelling of GMOs and GM-Food. We may qualify such a policy design as substantial and intermediate, in comparison to, on the one hand, the permissive policy implemented by the United States of America or Canada and, on the other, the restrictive policy adopted by Switzerland or Germany.

The pioneer status of Belgium in the development of biotechnologies, whether they come from biomedicine or the GM agro-food domain, could lead one to think that there is a convergence of their respective biopolicies. Yet this is not the case. The approach to the social problem that they seek to solve is identical: avoiding the negative effects of new biotechnologies, while favouring their positive applications. Moreover, the political regulation of ART and GMO concerns stakes that are values and beliefs, thus potentially conflicting. The role of values and beliefs in the policy-making process is evaluated by P. Sabatier and H. Jenkins-Smith in their famous Advocacy Coalition Framework (ACF) (6). This approach emphasizes the values and beliefs of policy-makers and the networks of these actors that develop within policy domains. The ACF operationalizes these policy networks, comprising coalitions of actors working in concert to achieve mutually desired ends. The role of values,

beliefs, interests and resources is central to the constitution of the policy coalitions. In such a theoretical framework, values and beliefs are ideas about or mental images of how the world is structured, how it works and how it should work.

In the ART-field, a profound dissension can be observed between the values and beliefs (ethical and philosophical or religious) of the policy actors, because the latter belong to various sociological pillars that characterise Belgian society and political culture. In particular, the polarisation between the Catholic and Secular pillars is very marked. This opposition clearly manifested itself during the controversial debate on the decriminalisation of abortion (law of 3 April 1990). In spite of the existence of this profound cleavage, the design process in the ART matter is not at all conflicting, not even for the public (for more details, see below).

In the GMO-field, the dissension between the actors involved in the policy network is also articulated along the lines of a values and beliefs conflict (socio-economic and environmental in nature). In this case, the design process is very conflicting, opposing two "advocacy coalitions" (6), whose views seem to be irreconcilable (for more details, see below).

From a comparative point of view, the biomedical sector and the GM food sector show at least one similarity: the decision-makers intervene to regulate biotechnology sectors that raise economic issues and involve fundamental bioethical questions. Conversely, the empirical analysis of the design processes and the constitution of the policy networks show significant differences in the political treatment of these conflicts of values. In short, the question we address in this article is why the ART-policy is far less interventionist than the GMO-policy in Belgium.

Theoretical framework and methods

In order to explain the content of the biopolicies regulating ART and GMO in Belgium (the dependent variable of our analysis), we adopt the *theoretical* perspective of "actor-centred institutionalism" (7). We thus start from the peculiarities of each biotechnological sector, and first and foremost from the actors who constitute the policy network. After having compared the structures of the networks belonging to the ART and GMO sectors, we will look in detail at the arenas and institutional rules that the various policy actors have mobilised, both on the national and international levels, in order to promote their policy position. Thus, in our theoretical framework, we identify three very rough categories of factors

TABLE 1
"From the laboratory to the market": Comparison of the ART- and GMO-Policies in Belgium

ART (procedural and permissive policy design)			**GMO (substantial and intermediate policy design)**		
ART chain	**Regulatory framework**	**Objectives and instruments of public policy**	***GMO chain***	**Regulatory**	**Objectives and instruments of public policy**
Research on embryos, stem-cells, cloning	Law of 11 May 2003 concerning research on *in vitro* embryos	To insure the liberty of research through Authorisations (art. 3), Prohibition (art. 5), Report (art. 9), Sanctions (penal disposals: art. 13 & 14)	***Contained use (laboratory work)***	Directive 90/219/CEE Adapted: 98/81/CE Brussels: 8 Nov. 2001 Flanders: 24 March 1998 Wallonia: 4 July 2002	To organise the prevention of risks linked to the confined use of GMO with the aim of protecting human healt hand the environment (art. 1) through regional authorisations and federal inspections

TABLE 1
"From the laboratory to the market": Comparison of the ART- and GMO-Policies in Belgium

ART (procedural and permissive policy design)			**GMO (substantial and intermediate policy design)**		
ART chain	**Regulatory framework**	**Objectives and instruments of public public**	***GMO chain***	**Regulatory**	**Objectives and instruments of policy public**
ART treatments	Three royal decrees (RD) of 15 February 1999 concerning a.o. the qualitative assessment of the medical activity in hospitals and fixing the criteria of programming applicable to the program of "reproductive medical" care	To guarantee the quality of health care and restrict access to the ART market for the centres through Authorisations (art. 2 RD fixing the criteria), Reports (art. 8 RD concerning the Physicians' College), Sanctions (art. 2 fixing the list of "reproductive medical" care)	***Deliberate release (field experiments)***	Directive 90/220/CEE Repealed: 2001/18/CE RD of 18 December 1998 (new RD: proposal awaited)	To organise the evaluation of the bio-safety of the products targeted by directive 90/220 (art. 1 of the RD) through federal authorisations and inspections
Social Welfare	RD of 4 June 2003 modifying the royal order of 25 April 2002 concerning the settling and the liquidation of the budget of the financial means of hospitals	To avoid the expense of multiple pregnancies through Funding of IVF and ICSI (art. 11)	***Marketing (production and commercialisation)***	Directive 90/220/CEE Repealed: 2001/18/CE RD of 18 December 1998 (new RD: proposal awaited)	To protect the consumers through federal authorisations and inspections (implementation of labelling and and traceability)

that might comprehensively explain the divergence of biopolicies across sectors. These independent variables are strongly related to three traditional comparative approaches to the study of politics and public policies in general (8): they might be titled the "Policy Sector Approach" (9, 10), the "National Patterns Approach" (11, 12) and the "International Regime Approach" (13).

From a *methodological* point of view, we analyse the interests, beliefs and values of the following policy actors: political decisions-makers (e.g. political parties, government coalitions); implementers of the rules-in-use (e.g. federal and regional administrations); social groups that are targeted by the policy instruments (e.g. ART-sector hospitals, physicians and researchers; GMO-sector researchers, producers and retailers) and end beneficiaries of the two biopolicies (e.g. patients, feminists, churches in the ART-sector; consumers and environmental associations in the GMO-sector). Furthermore, we take into account the institutional rules providing both opportunities and constraints for these actors who seek to design an ART- or GMO-policy within different decision-making arenas (e.g. legislatures, executives, courts, regulatory agencies, committees, etc.) at both national and international levels.

In concrete terms, we identify the main actors of the policy network in the ART-sector by analysing the content of official documents (e.g. bills, laws, parliamentary debates, administrative reports), and conducting interviews with 13 experts from the political-administrative sector, medical and research sector and voluntary associations. We also applied the so-called "reputation" approach (14) to identify the network of actors concerned by the public regulation of ART. To this end, we gave a questionnaire to the experts consisting of a list of 97 organisations -identified during our preliminary documentary analysis- divided into five categories: hospitals, pressure groups, political parties and public authorities at the federal level and the federated levels. Table 2 lists the actors who, according to the opinions of the experts, constitute the core of the policy network and have the greatest influence on the design process.

This data triangulation clearly shows that the most influential leaders in the design process are located both in the political field (the Socialist and Liberal Parties, the special Senate Commission on Bioethics) and in the medical field (various hospitals and the National Bioethics Committee of which the key members are physicians and researchers). Thus, it seems appropriate to focus our explanations of the ART-policy mainly on the role of political actors (parties, members of parliament) and on medical actors (practitioners, hospitals).

TABLE 2
Most influential policy actors in the ART-field

Nominations	Actor's name	Weighted score
5	Cliniques universitaires de Bruxelles- Hôpital Erasme (ULB)	0.3839
5	Comité consultatif national de bioéthique (CCNB)	0.3244
4	Akademisch ziekenhuis van de Vrije UniversiteitBrussel (VUB)	0.3172
4	Parti socialiste (PS)	0.3097
4	Institut de Morphologie-Pathologie de Loverval	0.2930
3	Belgian Register for Assisted Reproduction (BELRAP)	0.2530
3	Mouvement Réformateur (MR)	0.2263
3	Centrum voor Menselijke Erfelijkheid van de Katolieke Universiteit te Leuven (KUL)	0.2177
3	Commission spéciale chargée des problèmes bioéthiques score	0.2177

Note: The experts consulted identified 26 influential actors among the 97 ones proposed in the questionnaire. Among these 26 actors, we selected the 9 most influential ones according to the weighted scores of their reputation as powerful actors.

With a similar aim of explaining the GMO-policy, we apply the same methodology as for the ART-sector. A reputation analysis allowed us to circumscribe the network of the most influential actors during the decision-making process. After a first documentary analysis, we interviewed 11 experts in the GMO field. These experts were from political-administrative, academic, industrial and associative sectors. We also gave them a questionnaire containing a list of 91 organisations divided into six categories: university research centres, pressure groups, private companies, political parties and public authorities at the federal level and at the federated level. Table 3 shows the list of 13 actors that make up the core of the network according to the opinions expressed by the experts in the questionnaire.

This reputation analysis indicates that the core of the network is composed of actors who belong to political (Green parties), industrial (Bayer, Monsanto, EuropaBio) and academic sectors (VIB, Gembloux and KUL) as well as to environmental NGOs (Greenpeace, Nature et Progrès) and to consumer watchdog organisations (Test-Achats). This proves that the GMO-issue is relayed among all social arenas (with the notable exception of farmers, whose influence is not highlighted by the reputation analysis). This also applies to the 37 other actors forming the global policy network.

TABLE 3
Most influential policy actors in the GMO-field

Nominations	Actor's name	Weighted score
11	Anders Gaan Leven (AGALEV)	0.3409
11	Bayer CropScience (ex-Aventis)	0.3409
11	Ecologistes Confédérés pour l'Organisation de Luttes Originales (ECOLO)	0.3409
11	GreenPeace Belgium	0.3409
11	Vlaams Interuniversitair Instituut voor Biotechnologie (VIB, Gent)	0.3409
10	Nature et Progrès	0.3123
10	Cabinet du Ministre fédéral de la Protection des consommateurs, de la santé publique et de l'environnement	0.2992
10	Conseil de Biosécurité, Section de Biosécurité et Biotechnologie (SBB)	0.2992
10	Faculté universitaire des sciences agronomiques de Gembloux	0.2992
10	EuropaBio	0.2933
10	Monsento Services International S.A.	0.2933
9	Test-Achat	0.2669
9	Katolieke Universiteit Leuven (KUL)	0.2563

Note: The experts consulted identified 37 influential actors amongst the 91 proposed in the questionnaire. Among these 37 actors, we selected the 13 most influential ones according to the weighted scores of their reputation as powerful actors.

Results: comparative explanations of the ART- and GMO-policy

We will now systematically discuss the three categories of independent variables (Policy Network, National Patterns and International Regimes) formulated with the aim of explaining the contents of the policy designs adopted in the ART- and GMO-sectors. This set of hypotheses will allow us to understand why, in Belgium, the policy design with respect to ART is qualified as procedural and permissive, while the policy design with respect to GMO is qualified as substantial and intermediate.

"Policy community" in the ART-field versus "Issue network" in the GMO-field

The reputation analysis has allowed us to identify the policy networks of these two sectors, as well as the most influential actors at the heart of each (Tables 2 and 3). Taking the typology of March & Rhodes (15), table 4 shows that the actors' network of ART looks very much like a "policy community", while the GMO network is of the "issue network" type.

TABLE 4
Types of policy networks for the ART and GMO-fields

Dimensions of the policy networks		**ART-field: 'policy community'**	**GMO-field: 'issue network'**
Membership	**Number of participants**	*limited:* medical sector (university hospital and clinics), a few political entrepreneurs from socialist and liberal parties and Senate Commission	*large:* private biotech firms and economic associations, environmentalist groups, consumer associations, scientific researchers from universities, political entrepreneurs from green parties and an administrative agency (SBB)
	Types of interests	Professional interests of *physicians and researchers* clearly dominate	*Broad range* of competing research, economic, environmental and social/democratic interests
Integration	**Frequency and continuity of interaction**	*Frequent and high quality* of interaction between physicians (e.g. through the National Council for Bioethics, the Physician's college) and contacts with the politicians (Senate Commission) especially of their respective sociological 'pillar' (counsellors)	Access to the network *fluctuates* in time (e.g. sporadic and non-institutionalised actions of environmentalist groups) and contacts fluctuate in frequency and intensity (e.g. crisis periods)

TABLE 4
Types of policy networks for the ART and GMO-fields

Dimensions of the policy networks		**ART-field: 'policy community'**	**GMO-field: 'issue network'**
	Consensus or conflict on values and core beliefs	*Consensus:* Participants do not share the same values and beliefs (e.g. ontological status of embryo, family model), but they agree to 'live and let live' and, thus, they adopt a cooperative 'tit for tat' strategy based on a bioethical pluralism	*Conflict:* Participants disagree on basic values and beliefs on the manipulation of living organisms, the usefulness of GMOs for agriculture and development aid, the risks of GMOs for health and the environment, etc. and they radicalise their policy position
Distribution of resources	**within the network**	Expertise clearly in the hand of the *physicians* (whom politicians are dependent on) and *little* transparency about ART practices	*Competing* expertise of bio-molecular biologists and other scientific experts (whom politicians are dependent on) as well as divided civil society and *transparency* about deliberate releases of GMO
	within the partic-ipating organisations	*Hierarchical* (through local bioethics committees) and organisation of (university) hospitals	*Loose* organisation of environmentalists, retailers and consumers groups
Power and decision-making style		*Balance* of power between the members (sociological pillars), and positive sum game (if the policy community is to persist)	*Unequal* (but fluctuating in time) power of pro and contra-GMO, and zero-sum game (defeat of the other side of the issue network as goal)

Source: adapted from Marsh and Rhodes (1992:251)

Obviously, the structures of the policy networks in the ART- and GMO-sectors are different. They are even located at opposing ends of the continuum that Marsh & Rhodes suggest (16)[2]. This different structuring of the policy actors helps us to understand the divergence of the design process in the field of ART and of GMOs. The design process of the ART-policy is characterised by a high number of non-decisions (control of the agenda-setting and the decision-making process by a small number of actors, all of them experts in the biomedical sector)[3]. The design process of the GMO-policy is characterised by various successive and hotly debated decisions (repeated conflicts between social groups during the agenda-setting and the decision-making process).

But, as rightly underlined by Dowding (18), we cannot immediately conclude that the various network types linearly lead to different policy designs and policy outcomes. To establish such a link, we have to study the concrete interactions between the actors of the network during the design process: "'policy community' and 'issue network' are merely labels attached to an explanation of differences between policy formations in different sectors. The labels do not themselves explain the difference. The explanation lies in the characteristics of the actors" (19).

Thus we can concentrate on the interests and beliefs of policy actors as well as their relationship of co-operative exchange or, on the contrary, of confrontation (Table 5). The target groups of the ART-policy are clearly physicians and researchers. These actors, even if they do not share the same values and interests, nevertheless decide on concerted action with the aim of limiting all public intervention. The self-regulation of their practices, at the decentralised level of all ART-centres that display great bioethical pluralism, is politically acknowledged as a credible alternative to a public debate that would be seeking to harmonise ART-practices in Belgium. This "corporate" management of (the problems raised by) ART has never been challenged by the actors that are external to the sector. Indeed, the absence of mobilisation of the final beneficiaries (e.g. patients) as well as a public opinion that generally views biomedicine as favourable (positive risk-benefit balance), constitute an advantageous context for the

[2] Rhodes (17) defines a policy network as a cluster of organizations which are interconnected by resources dependencies. He distinguishes five types of policy networks along a continuum: (1) tightly integrated policy networks, (2) professional networks oriented towards their interests, (3) intergovernmental networks able of penetrating other networks, (4) producer networks where the economic interest plays a leading role for policy making and (5) loosely integrated issue networks with a large number of members.

[3] The non-decision process is illustrated by the fact that since the eighties, dozens of bills aiming at regulating ART have been proposed in Parliament without being adopted.

absence of a policy (until 1999), for political regulation above all of a procedural nature (the procedure takes the shape of official recognition of the ART-Centres and reimbursement of expenses for the patients) and, finally, for the legal consecration of the liberty of biomedical research (law of 11 May 2003 on *in vitro* embryo research).

The weak presence of administrative actors at (the core of) the policy network is an additional point to be highlighted. The tasks of conception, implementation and control of the policy are de facto largely delegated to bodies that are mainly composed of physicians (e.g. the National Bioethics Committee, the Physicians' College, the Federal Commission for the Medical and Scientific Research on *in vitro* Embryo). Given the centrality of the medical context in the entire design process, it is hardly surprising that the policy design is "permissive", leaving it to the discretion of each ART-centre to self-regulate its practices and, consequently, to potentially exploit the legal possibilities of research and therapies according to the law of 11 May 2003.

On the contrary, the target groups of the public GMO regulation, most notably the private companies and scientific researchers, find themselves in a markedly different position. The interviews that we have carried out show that, by and large, they share the same values and interests. Meanwhile, the scientific community is more divided nowadays than during the past decades with regard to the expected benefits and potential risks of GMOs. Last but not least, public opinion is very critical of green biotechnologies (negative risk-benefit balance) and one might also wonder whether the policy design directly mirrors the attitudes of the citizens[4].

Private companies and scientific researchers also seem incapable of proposing self-regulation of the sector. Moreover, they have to face the strong organisation and mobilisation of the various end beneficiaries of the policy design, which are primarily the associations of environmental

[4] Considerable research has already been done regarding media coverage and individual attitudes towards biotechnology over the last three decades (1, 2, 20). Unfortunately, for ART there are no comparable longitudinal data on public opinion. Thus it is difficult to explain the variation of policy designs across policy domains (ART versus GMOs) and across countries by individual attitudes of citizens. Nevertheless, Midden et al. (21) have classified attitudes per country on the basis of the 1996 Eurobarometer survey by looking at the extent to which individuals believe that the further development and use of six biotechnology applications (xenotransplants, food production, lab animals, crops plants, medicine and genetic testing) should be encouraged. This study shows that there is a tendency for countries with more negative attitudes towards the encouragement of biotechnology applications to have more restrictive policy designs and vice versa. But this co-variation of attitudes and policies says nothing on the causal mechanism and need to be interpreted.

and consumer protection. With the Biosafety Council and its minister in charge of acting as intermediaries, the State thus claims a role of referee between the two "advocacy coalitions", and of mediation of conflicts of interest. The "intermediary" character of the policy design represents a kind of middle way between the positions of the defenders and the opponents of GMOs.

TABLE 5
Mobilisation of private actors in the ART- and GMO-fields

Mobilisation of 'private' actors	**ART-field**	**GMO-field**
Self-regulation of target groups?	Strong divergences between the medical self-regulation organised in each "pillar" (as local committees of clinics and hospitals are more important than the National Council of Physicians for everyday practice) but cooperative strategy at the sector level	No vertical integration of the whole production chain: uncertainty regarding the attitudes of consumers and farmers that hamper self-regulation of the sector; no agreement within the scientific community
Public mobilisation of beneficiaries?	No collective action at all of ART patients, feminists/homosexuals or Christian groups; Indirect and localised support of physicians through ART-patients organisations	Very intensive action of greens movements (Green-Peace, Nature et Progrès) and consumer watchdog associations (Test-Achats); Direct and global confrontation between various associations and GMO producers
Supportive public opinion?	High and constant (e.g. from 1996 to 2002, genetic tests are supported by more than 90% of the Belgians)	Low to medium, but fluctuating (e.g. in 1999, GM-Food was supported by a minority of 47%)

This brief analysis of the interaction of actors involved in the ART and GMO sectors stresses the fact that, beyond this, structural data on the actors present and the decision-making modes differ greatly. Scharpf (22) lists three types of potential relationships between the actors of a policy network. They can be "competitive" (when the actors have incompatible interests), "indifferent" (when they try to avoid dependence on other actors) and "cooperative" (when they have common interests and trust each other). These three types of relationship imply three different decision-making styles: *Confrontation* refers to competitive interactions in which winning, or the defeat of the other side, has become the paramount goal, and in which the battle can typically be decided only by

superior powers or force. In a *bargaining* relationship, by contrast, individualistic participants are unconcerned about the relative advantage of the other side, and exclusively motivated by their own utilitarian self-interest. The typical outcome is compromise. *Problem-solving*, finally, implies the pursuit of common goals and the cooperative search for solutions that are optimal for the group as a whole" (23). In any case, the GMO sector is characterised by confrontation between various actors, polarised at the heart into two coalitions, while the ART-sector reflects a problem-solving situation in which a limited number of actors participate.

Focusing on the values and interests of the actors, we have briefly demonstrated the links that exist between one type of policy network, one type of decision-making and one type of policy-design. Hitherto, we haven't explicitly dealt with the influence of institutional rules, both at the national and at the international level.

Party politics and multi-level governance

With the aim of integrating institutional dimensions belonging to the Belgian political system, we will now focus the analysis on "party politics", the weight of federalism and, to a lesser extent, the administrative inter-policies coordination. Table 6 shows how these institutional factors influence –in both positive and negative directions– the political regulation of ART and GMO in Belgium.

The political parties play a key role in the regulation of the two sectors. The comparison of the design process highlights the decisive weight of the secular coalition (as from 1999) for ART and of the green parties (as from 1999) for GMO. In the first case, liberal and socialist senators use the arena of the Senate to enforce the agenda-setting and the decision-making connected to research on embryos. In the second case, it is the ministerial position of Agalev representatives (Ministry of Public Health, Consumer Protection and the Environment) which seems crucial in the reform, not only of the authorisation of deliberate GMO releases, but also in the reform of the very conception of the policy. In short, the contents of the policy design depends on a partisan struggle that, obviously, leads to the adoption of the policy design in agreement with the (partisan) ideologies and the (electoral) interests of their political promoters. On the one hand, the secular parties support a slightly interventionist policy with regard to ART, while, on the other hand, the ecologist parties promote a more interventionist regulation with respect to GMO.

TABLE 6
Relevant polity dimensions in the ART- and GMO-fields

Polity dimensions	**ART-field**	**GMO-field**
Party politics at federal level	- Christian-Democrat Parties (coalition leader until 1999) kept the issue deliberately off the agenda in order to avoid a party split or a division of the government coalition; - Liberals, Socialists and Green Parties ("secular coalition" since 1999) have rapidly adopt a permissive ART Policy	- Government parties (until 1999) supported GMO as a promising economic sector - Green parties – Agalev and Ecolo (since 1999) – have put the GMO issue on the public agenda and adopt a very restrictive regulatory practice
Federalism: Multi-level governance	No inter-ministerial or inter-regional coordination in the ART sector and, fierce competition between ART-Centres located in different provinces and regions	The Biosafety Council as a strong coordinator between the federal and regional levels, as well as between the agricultural, environmental and public health sectors
Inter-policy coordination	Limited agenda capacities for all bioethical issues: euthanasia has a higher priority; The Special Senate Commission as the arena for political debate (agenda control function)	GMOs socially and politically constructed as a new potential food crisis (BSE, dioxin, etc.); no specific arena for political debate (agenda 'explosion')
Administrative Agency	Nothing, low capacity-building (but 'private' agencies as the National Bioethics Committee, the Physicians' college, the Federal Commission according to the law of 11 May 2003)	The Biosafety Council as a central actor, gradual capacity-building (institutional design)

Beyond the above-mentioned party-political influence, it has to be noted that the federalist structure of Belgium and its administrative organisation also partly explain why the policy designs of the two sectors diverge upon comparison. As discussed below, federalism clearly seems to be an obstacle during the decision-making process in the ART sector, while it is rather like a driving motor in the GMO sector. This situation can be explained by the strategic mobilisation of one institution on one level of power by one actor of the policy network (e.g. the division of the ART-centres acknowledged in 1999 according to the existing provinces, or the mobilisation of the municipalities opposed to GMO by the organisation Nature et Progrès).

Moreover, it seems that the distinction between jurisdictional federations and functional federations (24, 25) is important here. The distinction between these two types of federations rests upon the method of division of competencies between the federal government and the sub-federal governments. In jurisdictional federations, full competencies in specific sectors are attributed to each level of government. In their respective areas of exclusive jurisdiction, governments can act unilaterally in jurisdictional federations. This is the case for GMOs, where their contained use depends on the Region in question, while the deliberate release of GMOs depends on the federal state (the authorization of the regional minister being a prerequisite).

In a functional federation, competencies are attributed along the functions of policy formulation and policy implementation. While formulation is normally the responsibility of the federal government, policy implementation usually belongs to sub-federal governments. This is the case for ART: the federal level decides on the programming (e.g. number of ART centres) and the Regions have delivered the official licence to ART centres since 1999. The federal State also controls *ex post* the quality of care as a result of the recent creation of the Physicians' College.

In contrast to jurisdictional federations, functional federations normally require intensive inter-governmental cooperation. Yet, in the two sectors that we are comparing here, the opposite is true. There is no multi-level coordinating organ for ART (this would be necessary to have a coherent policy), while the Biosafety Council is in charge of this task for the GMO sector (virtually exclusively). The existence of a political-administrative structure surely represents one of the conditions for an interventionist public policy. It is thus not surprising that, in the ART sector, the representatives of the medical sector have appropriated the tasks of implementation and control (e.g. by the Physicians' College) and, hence, contribute to the legitimacy of a "permissive" policy design.

The various effects that the mobilisation of certain federalist rules has on the regulation of ART and GMOs, are reinforced by differences connected to the political-administrative capabilities in these two sectors. Indeed, the arena of debate and coordination of the biomedical stakes has been limited to the Parliament and especially to the special Senate Commission on bioethics. This body plays a *de facto* filtering role for access to the decision-making process, just as it proceeds to sequencing – rather than coupling – the debates on bio-ethical questions. This process enhances the capacity of the actors (practitioners and researchers) to influence this body (in particular) for adopting a policy

design that is compatible with their interests. Indeed, practitioners and researchers are the main experts heard by the Parliament.

Conversely, the institutional arenas (e.g. the Biosafety Council, the Federal Agency for Food Safety, the Parliament) and extra-institutional arenas (e.g. the media, street demonstrations, the rooting-up of experimental fields) that the opponents of GMOs invest in, are multiple and varied. This makes the regulation more open and also allows the coupling of GMOs with previous agro-alimentary crises. Baumgartner and Jones (26) argue that the existence of many "institutional venues" in a country yields opportunities for "policy entrepreneurs", who are seen to use the different venues for strategic policy-making. The potential opportunities for policy entrepreneurs are increasing with the developing number of policy arenas. This hypothesis seems completely plausible in the case of GMOs in Belgium: indeed, the multiplication of the arenas and institutional rules mobilised offer the possibility, for the opponents of GMOs, to have their point of view heard, and, ultimately, to have an "intermediate" policy design adopted.

Finally, we address the question of whether international regimes have influenced the policy design in the ART and GMO sectors.

Europeanisation by changing the structure of opportunities

The international context, in which the design process of the ART- and GMO-policies has been developed, is also very different. And this influence seems to be decisive for the substantial contents of the policy designs (Table 7). In the case of ART, there is no institutional constraint to harmonise Belgian policy with supranational norms. The Convention on Human Rights and Biomedicine of the Council of Europe (1997) and the Additional Protocol on the Prohibition of Reproductive Cloning (1998) have been ratified and signed on a voluntary basis. Conversely, in the case of GMOs, the European Directives on contained use of GM Micro-organisms (revised 90/219/EEC: 98/81/EC) and on deliberate release (repealed 90/220/EC: 2001/18/EC) must be transposed into Belgian law. This difference seems fundamental in the sense that the domestic actors are not capable of withdrawing from this international framework.

The question of embryo and cloning research has been put on the Belgian political agenda partially because of the Biomedicine Convention. However, its restrictive article 18 (which prohibits the creation of embryos for scientific purposes) has not been supported by a sufficient majority of votes to sign and ratify the Convention. On the contrary, it has had a

triggering effect in the sense that Belgium adopted a national law in 2003 that deals with this issue, but that ratifies a solution that is markedly more liberal than the one initially proposed by the Convention. In other words, the Belgian political entrepreneurs made a deliberate choice to first vote for a permissive law (also with the aim of keeping the best researchers in Belgium) and, subsequently, to possibly ratify the Convention by expressing their reservations (using art. 36 of the Convention) about art. 18.

TABLE 7
Relevance of global factors in the ART and GMO-fields

Globalisation dimensions	**ART-field**	**GMO-field**
Top down harmonisation?	*Voluntary* policy transfer (European Convention): impact on agenda-setting but not on policy designing	*Coercive* policy transfer (European directives): "Europeanisation by changing domestic opportunity structure"
Policy transfer?	No lesson-drawing across Regions, countries or health-related sectors	Federal Food Safety Agency and "consensus conference" (April 2003) inspired by the French regulatory framework

However, in the GMO sector, the influence of the European directives is clear. The process of "Europeanisation by changing domestic opportunity structure" seems even more plausible since it is happening in a sector where the actors of the policy networks are very polarised. "Héritier and Knill (27) argue that the potential European impact on national regulatory styles and structures increases with the extent to which a domestic policy context is characterised by a *contested interest constellation* and a relatively *even distribution of powers and resources* across opposing actor coalitions. In view of such balanced constellations, European-induced changes in domestic opportunity structures are potentially more likely to tip the scales in favour of one actor coalition, hence triggering regulatory reform" (28). Indeed, directive 2001/18/CE seems to have opened a political "window of opportunity" for the camp of the opponents of GMOs. They have tried to "instrumentalise" the future 2001/18/CE in order to legitimise their arguments and to enforce Belgian regulation (e.g. by introducing the ethical evaluation of deliberate releases that go beyond the risk assessment for health and environment practised hitherto).

In both ART and GMOs cases, the supranational norms were translated into national law according to the values and interests of the

dominant Belgian policy actors (Table 5) in the sense of either a less (ART) or a more restrictive (GMOs) regulation.

Finally, it has to be noted that certain foreign experiments have also been the object of a re-appropriation and of a "policy transfer" (29) by certain Belgian actors. Thus, both the creation of the Federal Agency for Food Safety and the implementation of a "consensus conference" have been directly inspired by previous French practices. Indeed, these two processes of "lesson-drawing" tend to enlarge the debate on GMOs: by both coupling GMOs with food crises and by directly involving citizens in the political debate. These two factors have indirectly contributed, through their strategic valorisation and the media attention they have received, to the adoption of a policy design qualified as "intermediate".

Discussion

As a preliminary conclusion of this brief comparative analysis, we underline the importance of considering (alongside one another) sectors' characteristics, national arenas and international rules. The two Belgian executive case studies presented in this article tend nevertheless to demonstrate that the structuring of the policy actors, at the sector level, lies at the heart of the explanation of the policies finally adopted. The agenda-setting and decision-making arenas and the institutional rules have allowed, even reinforced, the strategies followed by the dominant actors of the policy network. One key example of this is the continued mobilisation of the Biosafety Council as a multi-level coordination body versus the creation of bodies representing the interests of physicians to overcome the absence of an administrative structure in the health sector. A further example is the anticipated application of European GMO directives *versus* the substitution of the European Convention on Biomedicine by a more permissive Belgian law. In short, a well-founded explanation of the political regulation of biotechnologies in Belgium could not escape a detailed analysis of: a) the influential actors at the heart of the sector concerned, b) the interests and values they defend and, finally c) the winning strategies they use to have a policy design formulated according to their policy positions.

Therefore, if we intend to seriously analyse the design process of the Belgian policy on genetic testing (or any other biotechnology), we have to look in detail at the various stakeholders involved. We expect that the (degree of restrictiveness of the) regulation on genetic testing will depend, on the one hand, on the interests, beliefs and values of the social groups engaged in the political debate (e.g. labour, industrial

management, physicians at the work place, scientific researchers, insurance companies, etc.) and, on the other hand, on the resources, institutional arenas and rules these policy actors can mobilise in order to gain access to the sector network designing the policy. Obviously the interests and social positions of labour and industrial management diverge. Workers are generally in favour of genetic monitoring (to promote preventive medicine), but not in favour of genetic screening (to avoid discrimination on the jobs market). On the contrary, industrial management supports genetic screening, but opposes genetic monitoring. Generally speaking, we may postulate that industrial management tends to be concerned about high-risk workers, while labour tends to focus more on the conditions of hazardous work. Thus, the re-distributive impact of any public policy on genetic testing will be significant and thereby, trigger political controversy. As already stated by Draper (30): "Emphasising conflicting interests at first may seem to be a sociological truism, but this is a powerful perspective infrequently found in the literature on risk, new technologies or occupational health. It is important to ask: In whose interests are specific practices and orientation towards risk? What are the risks of these practices and who experiences them? What is the relative power distribution among groups that affects industrial policy and the divergent views toward risk? This focus on conflicting interests and power in analysing the shifting conceptions of occupational hazards has certain implications for policy and for recasting the problem of workers at risk". A systematic analysis of the agenda-setting and policy-formulation in the field of genetic testing would contribute to our understanding of the political regulation of biotechnologies in Belgium and, furthermore, of the development of biopolitics.

Despite the considerable amount of political activity and public attention surrounding biopolicy issues, there is a deficit in political science research on this topic (3). For example, the link between individual attitudes towards biotechnology, the public opinion on red and green biotechnology applications and the content of biopolicies is not well established by empirical studies. Furthermore, while the policy approach adopted in this article certainly provides a good description of the observed differences between the ART and GMOs regulations, it does not yet establish clear and definitive relations of cause to effects (e.g. relations between the type of network and the content of the policy design). Such a temporary deficit in policy research becomes apparent if we compare what has already been undertaken in the burgeoning areas of bioethics, biolaw and bioeconomics to the still missing –or at least underdeveloped– political science research on biopolitics. Comparative policy analyses of red and green biotechnologies should therefore be aimed at

closing this gap by addressing the key question of what political science might contribute to explaining politics and policy choices in the field of biotechnologies and what the discipline might also contribute to the ongoing public debates on which policy designs to choose.

References

1. Durant J, Bauer MW, Gaskell G. (eds.) Biotechnology in the Public Sphere, London: Science Museum, 1998.
2. Gaskell G, Bauer MW. (eds.) Biotechnology 1996-2000. The years of controversy, London: NMSI Trading Ltd, 2001.
3. Blank RH, Hines SM Jr. Biology and Political Science. London and New York: Routledge, 2001.
4. Bleiklie I, Goggin M, Rothmayr Ch. (eds.). Comparative Biomedical Policy. Governing Assisted Reproductive Technology, London: Routledge, 2003.
5. Casse-Delbart F. La transgénèse végétale, in Kahn A. (ed.) Les plantes transgéniques en agriculture. Dix ans d'expériences de la Commission du Génie Biomoléculaire, Montrouge: John Libbey Eurotext, 1996: 61.
6. Sabatier P, Jenkins-Smith H. Policy Change and Learning: An Advocacy Coalition Framework, Boulder: Westview Press, 1993.
7. Scharpf FW. Games Real Actors Play. Actor-centred Institutionalism in Policy Research, Boulder: Westview Press, 1997.
8. Levi-Faur D. Comparative Research Designs in the Study of Regulation: How to Increase the Number of Cases without Compromising the Strengths of Case-Oriented Analysis, Paper presented at the International Workshop of the Centre on Regulation and Competition, 4-6 September 2002, University of Manchester, 2002.
9. Freeman GP. National Styles and Policy Sectors: Explaining Structured Variation. J Public Policy 1986; 5 (4): 467-96.
10. Marsh D, Rhodes RAW. Policy Communities and Issues Network. Beyond Typology, in Marsh D, Rhodes RAW. (eds.) Policy Networks in British Government, Oxford: Clarendon Press, 1992: 249-69.
11. Richardson J. (ed.) Policy Styles in Western Europe, London: George Allen & Unwin, 1982.
12. Vogel D. National Styles of Regulation. Environmental Policy in Great Britain and the United States, Ithaca and London: Cornell University Press, 1986.
13. Krasner SD. International Regimes, Ithaca: Cornell University Press, 1983.
14. Laumann E, Knoke D. The Organisational State: Social Choice in National Policy Domains, Madison: University of Wisconsin Press, 1987.
15. Marsh D, Rhodes RAW. Policy Communities and Issues Network. Beyond Typology, in Marsh D, Rhodes RAW. (eds.) Policy Networks in British Government, Oxford: Clarendon Press, 1992: 251.
16. Marsh D, Rhodes RAW. Policy Communities and Issues Network. Beyond Typology, in Marsh D, Rhodes RAW. (eds.) Policy Networks in British Government, Oxford: Clarendon Press, 1992: 51.
17. Rhodes RAW. Understanding Governance. Policy Networks, Governance, Reflexivity and Accountability, Buckingham-Philadelphia: Open University Press, 2001 (reprinted): 36-42.
18. Dowding K. Model or metaphor? A critical review of the policy network approach. Political Studies, 1995; 43(2):136-58.

19. Dowding K. Model or metaphor? A critical review of the policy network approach. Political Studies, 1995; 43(2):142.
20. Bauer MW, Gaskell G. (eds) Biotechnology: The Making of a Global Controversy, Cambridge: Cambridge University Press, 2002.
21. Midden C. et al. The structure of public perceptions, in Bauer MW, Gaskell G. (eds) Biotechnology: The Making of a Global Controversy, Cambridge: Cambridge University Press, 2002.
22. Scharpf FW. Decision rules, decisions styles and policy choice. Journal of Theoretical Politics, 1989; 1(2):149-76.
23. Scharpf FW. Decision rules, decisions styles and policy choice. Journal of Theoretical Politics, 1989; 1(2):189.
24. Watts RL. Comparing Federal Systems, Kingston: Institute of Intergovernmental Relations, 1999.
25. Braun D. (ed.) Public Policy and Federalism, Aldershot: Ashgate, 2000.
26. Baumgartner FR, Jones BD. Agendas and Instability in American Politics, Chicago: University of Chicago Press, 1993.
27. Héritier A, Knill Ch. Differential responses to European policies: A comparison, in Héritier A. et al. Differential Europe: New opportunities and restrictions for member-state policies, Lanham: Rowaman & Littlefield; 2001: 257-94.
28. Knill Ch, Lehmkuhl D. The national impact of European Union regulatory policy: Three Europeanisation mechanisms. Eur J Polit Res 2002; 41: 255-80.
29. Dolowitz D, Marsh D. Learning from Abroad: The Role of Policy Transfer in Contemporary Policy-Making. Governance: An International Journal of Policy and Administration, 2000; 13(1): 5-24.
30. Draper E. High-Risk Workers or High-Risk Work? Genetic Susceptibility Policies in the Hazardous Workplace. Int J Social Soc Policy, 1986: 12-28.